

34.(Amended) A valve according to claim 1, wherein the valve is electro-magnetically or mechanically controlled independent of the pressure in the bladder to be emptied.

35.(Amended) A valve according to claim 1, wherein the valve may be opened by means of a opening force being between 10 to 200 mN.

36.(Amended) A valve according to claim 35, wherein the valve may be opened by means of a opening force being between 20 to 100 mN.

37.(Amended) A valve according to claim 30, wherein the valve is partly flexible, and partly rigid, whereby the rigid part is shorter than 50 mm.

38.(Amended) A method for emptying a patient's urine bladder, whereby a valve assembly in accordance with claim 1 is inserted in the urethra and influenced at time intervals to open and empty said bladder.

**REMARKS**

The present Preliminary Amendment is submitted in order to conform the claims to U.S. patent practice.

Examination on the merits is respectfully requested.

Respectfully submitted,



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MARKED UP CLAIMS AS AMENDED

CLAIMS

- 1.(Amended) A valve assembly adapted to be positioned into a urethra in a mammal, including humans, the valve assembly comprising:
  - a) a valve holder comprising a substantially cylindrically shaped body to be inserted into the urethra, and
  - b) a valve housing comprising a valve controlling an urine flow from a patients bladder, the valve assembly being 'arranged in a sealed manner between the walls of the urethra, [characterised in that] wherein the cylindrical valve holder [(1)] comprises a shape memory alloy to provide an expandable element having the possibility to expand after the insertion of said valve holder [(1)] to increase its diameter at its upper end [(2)] to provide a frustoconical portion, whereby the increase of the diameter of the cylinder at its upper end is more than 15 % and whereby the increase of the diameter of said cylindrical valve holder [(1)] is temperature dependent.
- 2.(Amended) A valve assembly according to claim 1, [characterised in that] wherein the cylindrical valve holder [(1)] increase its diameter at its lower end [(2)].
- 3.(Amended) A valve assembly according to claim 1[-2], [characterised in that] wherein the valve holder [(1)] comprises at least two frustoconically shaped portions [(2, 2)].
- 4.(Amended) A valve assembly according to [claims 2-3] claim 2, [characterised in that] wherein the valve holder [(1)] comprises at least two frustoconically shaped portions at one end of the cylinder.
- 5.(Amended) A valve assembly according to [claims 1-4] claim 1, [characterised in that] wherein the valve holder [(1)] comprises at least two frustoconically shaped portions at one end of the cylinder as well as at least one frustoconically shaped portion at the opposite end thereof.

6.(Amended) A valve holder according to [claims 1-5] claim 1, [characterised in that] wherein the holder [(1)] and the housing [(3)] are detachable from each other when in place in the urethra.

7.(Amended) A valve assembly according to [claims 1-5] claim 1, [characterised in that] wherein the holder [(1)] and the housing [(3)] are detachable from each other.

8.(Amended) A valve assembly according to claim 1, [characterised in that] wherein the valve holder [(1)] includes a first portion [(2)] exhibiting a frustoconical shape, a second portion being essentially cylindrical and a third portion [(2)] exhibiting a frustoconical shape directed in opposite direction in relation to the first portion.

9.(Amended) A valve assembly according to claim 1, [characterised in that] wherein the valve holder [(1)] includes a first portion exhibiting at least two parts having frustoconical shape, a second portion being essentially cylindrical and a third portion exhibiting a frustoconical shape directed in opposite direction in relation to the first portion.

10.(Amended) A valve assembly according to [claims 1-8] claim 1, [characterised in that] wherein the holder [(1)] is helix shaped wire arranged onto the valve housing.

11.(Amended) A valve assembly according to [claims 1-9] claim 1, [characterised in that] wherein the holder [(1)] comprises a helix shaped wire threaded on external threads arranged on the outside of the valve housing.

12.(Amended) A valve assembly according to [claims 1-10] claim 1, [characterised in that] wherein the increase of the diameter of the helix shaped wire at its upper end is more than 15 %.

13.(Amended) A valve assembly according to claim 11, [characterised in that] wherein the increase of the diameter of the cylinder at its upper end is at least 40 %.

14.(Amended) A valve assembly according to [claims 1-10] claim 1, [characterised in that] wherein the increase of the diameter of the helix shaped wire at its upper end is at least 40 %.

15.(Amended) A valve assembly according to [claims 1-14] claim 1, [characterised in that] wherein the increase of the diameter of the helix shaped wire at its upper end after expansion is at least 25 %.

16.(Amended) A valve assembly according to [claims 1-15] claim 1, [characterised in that] wherein the increase of the diameter of the helix shaped wire at its lower add is at least 10 %.

17.(Amended) A valve assembly according to [claims 1-16] claim 1, [characterised in that] wherein the increase of the diameter of the helix shaped wire at its lower end after expansion is at least 20 %.

18.(Amended) A valve assembly according to [claims 1-17] claim 1, [characterised in that] wherein the increase of the diameter of the cylindrical portion of the valve holder is less than 80 %.

19.(Amended) A valve assembly according to [claims 1-18] claim 1, [characterised in that] wherein said valve holder comprise an expandable element having the possibility to shrink upon removal of said valve housing.

20.(Amended) A valve assembly according to claim 1, [characterised in that] wherein the total length of the assembly is less than the length of the female urethra where it is intended to be inserted,

21.(Amended) A valve assembly according to claim 1, [characterised in that] wherein the total length of the valve is less than 60 mm.

22.(Amended) A valve assembly according to [claims 1-21] claim 1, [characterised in that] wherein the total length of the valve assembly is between 5 and 40 mm, preferably 5-30 mm.

23.(Amended) A valve assembly according to [any of claims 1-22] claim 1, [characterised in that] wherein at least a part of the length of the valve body of said valve assembly has a bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton square meter).

24.(Amended) A valve assembly according to [any of claims 1-23] claim 1, [characterised in that] wherein at least a part of the length of the valve body of said valve assembly has a bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton square meter) and that at least a part of the length of the valve body of said valve assembly has a bending stiffness lower than  $0.05 \text{ Nm}^2$  (Newton square meter).

25.(Amended) A valve assembly according to [any of claims 1-24] claim 1, [characterised in that] wherein the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton square meter) is less than 80% of the length of the female urethra where it is intended to be inserted.

26.(Amended) A valve assembly according to [any of claims 1-25] claim 1, [characterised in that] wherein the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton square meter) is less than 50mm.

27.(Amended) A valve assembly according to [any of claims 1-26] claim 1, [characterised in that] wherein the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton square meter) is less than 40mm.

28.(Amended) A valve assembly according to [any of claims 1-27] claim 1, [characterised in that] wherein the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton square meter) is between 5 and 60 mm.

29.(Amended) A valve adapted to be positioned into a urethra and in a valve assembly according to [claims 1-28] claim 1, said valve for emptying a patient's urine collected within his bladder, comprising: a tubular vane housing having an upper, lower, and central part and a channel therein; a valve body situated at the lower part of the housing a valve seat situated below said valve body, said central part having at least one drainage hole extending through said tubular housing, said drainage hole located in the area between the upper end and the valve seat, said channel of the valve housing in communication with said drainage hole, said valve body being arranged to be moved in a longitudinal [characterised in that] wherein the total length of the valve is less than 60 mm.

30.(Amended) A valve adapted to be positioned into a urethra and in a valve assembly according to [claims 1-29] claim 1, said valve for emptying a patient's urine collected within his bladder, comprising: a tubular valve housing having an upper, lower, and central part and a channel therein; a valve body situated at the lower end of the housing and attached to a valve rod which in an opposite end thereof comprises a magnet accommodated in the upper portion of the valve; and a valve seat situated below said valve body, said central part having at least one drainage hole extending through said tubular housing, said drainage hole located in the area between the upper part and the valve seat, said channel of the valve housing in communication with said drainage hole, said valve body being arranged to be moved in a longitudinal direction by means of a part of the valve rod extending below said valve rod.

31.(Amended) A valve according to [one or more of the preceding claims] claim 1, [characterised in that] wherein the valve housing comprises a magnetic controlled valve.

32.(Amended) A valve according to [one or more of the preceding claims] claim 1, [characterised in that] wherein the valve is electro-magnetically controlled.

33.(Amended) A valve according to [one or more of the preceding claims] claim 1,

[characterised in that] wherein the valve is mechanically controlled.

34.(Amended) A valve according to [one or more of the preceding claims] claim 1,  
[characterised in that] wherein the valve is electro-magnetically or mechanically  
controlled independent of the pressure in the bladder to be emptied.

35.(Amended) A valve according to [one or more of the preceding claims] claim 1,  
[characterised in that] wherein the valve may be opened by means of a opening force  
being between 10 to 200 mN.

36.(Amended) A valve according to claim 35, [characterised in that] wherein the valve  
may be opened by means of a opening force being between 20 to 100 mN.

37.(Amended) A valve according to [claims 30-36] claim 30, [characterised in that]  
wherein the valve is partly flexible, and partly rigid, whereby the rigid part is shorter than  
50 mm.

38.(Amended) A method for emptying a patient's urine bladder, whereby a valve  
assembly in accordance with [claims 1-37] claim 1 is inserted in the urethra and  
influenced at time intervals to open and empty said bladder.